Revised 510K Summary
K091812

MAY - 7 2010

The following information is provided as required by 21 CFR 807.87 for the 510(k) premarket notification for five plate and screw systems, Frontier Devices Maxillofacial System, Frontier Devices Orthognathic System and Frontier Devices Mandible Reconstruction System and Mesh System.

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|---|---|---|---|
| Date Prepared: | May 6, 2010 | | |
| Sponsor : | Frontier Devices<br>153A Cahaba Valley Parkway<br>Pelham, AL 35124 | | |
| FDA Registration #: | 3006803588 | | |
| Contact Person: | Don Petersen, Ph.D.<br>Director Quality Assurance and Regulatory Affairs<br>205-733-0901 (phone)<br>205-733-8445 (fax)<br>dpetersen@frontierdevices.com | | |
| Proprietary Names: | Frontier Devices Maxillofacial System<br>Frontier Devices Orthognathic System<br>Frontier Devices Mandible Reconstruction System<br>Frontier Devices Mesh System | | |
| Common Names: | Bone plates and screws | | |
| Classification Names:<br>(Regulation Number)<br>[Product Code] | Bone plate<br>Intraosseous fixation screw | (872.4760)<br>(872.4880) | [JEY]<br>[DZL] |
| Device Classification: | Class II | | |
| Panel: | Dental | | |

Predicate Devices

*Frontier Devices Maxillofacial System*

BioPlate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery (K030806)

*Frontier Devices Orthognathic System*
Ortrautek Orthognathic System (K031989)

*Frontier Devices Mandible Reconstruction System*
BioPlate Mandible Fixation System (K012910)

*Frontier Devices Mesh System*
Synthes Craniofacial Plate and Screw System (K050608)

Device Descriptions

*Frontier Devices Maxillofacial System*

The devices in the Maxillofacial System are implantable bone plates and bone screws for oral and maxillofacial procedures including fractures, osteotomies, orthognathic, reconstructive procedures and revisions procedures when other treatments of devices have failed.

Surgical locations for device placement includes fracture and reconstruction sites in the mandible, maxilla, zycomatic bone and orbital socket.

Plates range in shape and size to aid the surgeon in repairing bone. Plate shapes include Oblique L, T, Curve, Straight, Y, Double Y, Box, X, H and Z. The sizes for the plates range from 0.4 to 1.0 mm thick and up to 100 mm in length. Plates are made from medical grade unalloyed titanium (commercially pure Titanium grade 4, ASTM F-67).

The screws are made from alloyed titanium (Titanium 6Al 4V, ASTM F-136). The screws have two designs, a self-tapping screw that is to be used after pre-drilling pilot holes and a self-drilling screw that does not require a pre-drilled hole. Screws have diameters ranging from 1.5 to 2.3 mm and lengths from 3 to 24 mm.

*Frontier Devices Orthognathic System*

The Frontier Devices Orthognathic System consists of titanium bone plates and screws of various shapes and sizes. The plates are made from unalloyed titanium that conforms to the ASTM F67 standard. Plates range in shape and size to aid the surgeon in repairing the maxilla and mandible. Plate shapes include L-Tooth, L-Zigomatic, and Straight. The sizes for the plates range from 0.8 to 1.0 mm thick and up to 42 mm in length.

The screws are self-tapping screws that require a pre-drilled pilot hole and are made from a titanium alloy, Ti-6Al-4V, that conforms to the ASTM F136 standard. Screws are 2.0 to 2.7 mm in diameter and range in length from 6 to 22 mm.

This system provides a wide variety of specific screws and plates intended for use for maxillofacial trauma, maxillofacial, orbital reconstruction and specialized orthognathic surgery. The indications include mandible and maxilla trauma, reconstruction of the mandible or maxilla, intermaxillary fixation and orthognathic surgery.

Surgical locations for device placement includes fracture and reconstruction sites in the mandible and maxilla.

*Frontier Devices Mandible Reconstruction System*

The Frontier Devices Mandible Reconstruction System consists of titanium bone plates and screws of various shapes and sizes intended for use for maxillofacial trauma, maxillofacial, orbital reconstruction and specialized orthognathic surgery. The indications include mandible trauma, such as, severe comminution and bone loss and unstable mandible fractures; mandible reconstruction such as, bridging defects after tumor resection or severe infection; intermaxillary fixation, and orthognathic surgery.

Surgical locations for device placement includes fracture and reconstruction sites in the mandible.

The plates are made from unalloyed titanium that conforms to the ASTM F67 standard. Plates are 1.25 to 1.70 mm thick and up to 56 mm in length. The plates come in a variety of shapes and sizes to aid the surgeon in repairing the maxilla and mandible. Plate shapes include straight and angled.

The screws are self-tapping screws that require a pre-drilled pilot hole and are made from a titanium alloy, Ti-6Al-4V, that conforms to the ASTM F136 standard. Screws are 2.3 to 3.0 mm in diameter and range in length from 5 to 18 mm.

*Frontier Devices Mesh System*

The Frontier Devices Mesh System consists of titanium meshes and screws of various shapes and sizes. Reconstruction of maxillofacial defects can be carried out with titanium mesh to reconstruct the missing framework of the maxillofacial area. The defects can be caused by acute trauma, tumor removal, and previous operations. The Mesh System is indicated for immediate reconstruction in the primary treatment of comminuted fractures with bone loss in non load-bearing areas, treatment of contour irregularities (possibly in combination with bone or cartilage grafts), and applicability for orbital and sinus defects. The desired strength, contour ability and desired location are all factors that determine which size and thickness of mesh the surgeon selects.

Surgical locations for device placement includes fracture and reconstruction sites in the mandible, maxilla, orbital and sinus regions.

The meshes are made from unalloyed titanium that conforms to the ASTM F67 standard. Meshes are 0.45, 0.60 and 0.867 mm thick and come in a variety of shapes and sizes that are designed for mesh applications. The 0.4 mm thick mesh is less rigid and more contour-able and intended for small voids/defects. The 0.6 mesh is more rigid and is intended for larger voids/defects. The 0.87 mm mesh offers the greatest strength and is intended for larger defects.

The screws are self-drilling screws that do not require a pre-drilled pilot hole and are made from a titanium alloy, Ti-6Al-4V, that conforms to the ASTM F136 standard. Screws are 1.5 to 2.3 mm in diameter and range in length from 3 to 6 mm.

Intended Use:

*Frontier Devices Maxillofacial System*

Frontier Devices Maxillofacial System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

*Frontier Devices Orthognathic System*
Frontier Devices Orthognathic System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

*Frontier Devices Mandible Reconstructive System*
The Frontier Devices Mandible Reconstructive System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

*Frontier Devices Mesh System*
Frontier Devices Mesh System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Technology Characteristics
The plates and screws of the five different Frontier Devices systems have similar dimensions, designs and materials as the predicate devices The plates are between 0.4 and 1.7 mm thick, made from unalloyed titanium (ASTM F67) and have similar design shapes and sizes as the predicate devices. The screws are all made from titanium alloy (ASTM F136) with diameters between 1.5 and 3.0 mm and lengths of 3-22mm which are similar to the predicate devices.

Performance Tests
Performance tests on representative screws showed them to have similar results as predicate screws.

Substantial Equivalence
The Frontier Devices Maxillofacial, Orthognathic, Mandible Reconstruction and Mesh Systems consist of plates and screws that are identical in material composition and have the same indications for use as the relevant predicate devices. All of the technical characteristics are substantially equivalent to the corresponding characteristics of the predicate devices. There may be slight differences in dimensions and shapes between the Frontier Devices Systems and the predicate devices, however, these minor differences raise no new issues of safety and efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Don Peterson, Ph.D.
Director of Quality Assurance and Regulatory Affairs
Frontier Devices, Incorporated
153A Cahaba Valley Parkway
Pelham, Alabama 35124

MAY - 7 2010

Re: K091812
Trade/Device Name: Frontier Devices Maxillofacial System
Frontier Devices Orthognathic System
Frontier Devices Mandible Reconstruction System
Frontier Devices Mesh System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZL
Dated: April 30, 2010
Received: May 4, 2010

Dear Dr. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Form

## Indications for Use

510(k) Number (if known): **K091812**

Device Name: **Frontier Devices Maxillofacial System**

Indications for Use:

Frontier Devices Maxillofacial System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Prescription Use _____x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mruby for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091812

# Indications for Use Form

## Indications for Use

510(k) Number (if known): **K091812**

Device Name: **Frontier Devices Orthognathic System**

Indications for Use:

Frontier Devices Orthognathic System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

| Prescription Use _____x__ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mulay for MSR

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091812

# Indications for Use Form

## Indications for Use

510(k) Number (if known): **K091812**

Device Name: **Frontier Devices Mandible Reconstruction System**

Indications for Use:

The Frontier Devices Mandible Reconstructive System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

| Prescription Use _____x__ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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Concurrence of CDRH, Office of Device Evaluation (ODE)



Kevin Mackey for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091812

# Indications for Use Form

## Indications for Use

510(k) Number (if known): **K091812**

Device Name: **Frontier Devices Mesh System**

Indications for Use:

Frontier Devices Mesh System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Prescription Use _____x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page _1_ of _1__

Kevin Mackey for MSR

(Division Sign-Off)
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510(k) Number: K091812